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Division of Dockets Management, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

To Whom It May Concern:

This refers to the Draft Guidance for Industry and FDA Staff: Saline, Silicone Gel, and Alternative Breast Implants, issued January 13, 2004.

The requirements for long term assessment are very well directed. Had industry taken a similar but less formal request, recommended and discussed at the FDA hearing in January 1989, we would now have the currently requested ten (10) year database.

At the same time, permit me to suggest the addition of one further requirement: the submission of capsular tissue sections from all explantations or exchanges of devices over the entire period of time. These are available from pathology labs of hospitals or surgicenters where reconstructive surgeons commonly practice.


These could be required to be sent to an in-house FDA laboratory or to the Armed Forces Institute of Pathology silicone device registry (I assume it still operates). The reason for this suggestion is based on straightforward immunopathic principles, as noted in my letter to the Commissioner, October 13, 2003, to wit:

Siliconosis is an immunopathological reaction to the siloxanes of the polymers. This is because:

1. The lesions are similar to those of tuberculosis and berylliosis, which share T cell memory to chemical aspects of the respective injurious agent.
2. The lesions are textbook delayed hypersensitivity.
3. No epidemiological study has ever taken these facts into account.

Thanking you for your attention to this matter, I remain,

Sincerely yours,


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drs/hwp
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